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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/657,940 | 09/09/2003 | Jason D. Meridew | 5490-000341 | 1613 |

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| EXAMINER |
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SHAFFER, RICHARD R

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| ART UNIT | PAPER NUMBER |
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3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 12/26/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/657,940 | Applicant(s) MERIDEW ET AL. | |
| | Examiner Richard R. Shaffer | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16-21, 23-38 and 40-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The amendments to the claims filed on October 11th, 2006 are acknowledged and accepted by the examiner. The previous rejections under 35 U.S.C. 112, 2nd paragraph are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 21, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 recites the limitation "a slot." The apparatus has no support for both a channel and slot. It appears since applicant has previously used "aperture" and "slot" to define openings in bone in unrelated claims and states, "the slot is formed by translating the driver," that applicant is also positively reciting the human body. The limitations of claims 11 and 12 will be given no patentable weight during this state of prosecution.

Claim 20 as now amended recites, "a slot defined within the contoured surface." Claims 21, 25, and 26 all dependent upon claim 20 recites, "forming the slot." How is the slot "defined" within the pre-existing contoured surface AND formed afterwards by driving into bone? Applicant may wish to use language such as "partially defines" in

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claim 20 in order to continue claiming the limitations in the dependent claims or to cancel claims 21, 25 and 26 altogether. For examination purposes, the limitations of claims 21, 25 and 26 will be ignored due to new matter/non-enablement.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As explained in the 35 U.S.C. 112, first paragraph rejection, applicant appears to be positively reciting the human body.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 16-19, 36-38 and 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohrs et al (US Patent 6,224,631).

Kohrs et al disclose a cylindrical, resorbable (**Column 3, Lines 40-47**) implant/bone screw (**10, Figure 1**) having a threaded (**7**) exterior; a pair of opposed channels (**24a/b**);

[**First Interpretation**] a driver (**506, Figures 16 and 17**) also having a threaded/cutting portion (**526, 527**) and a driving portion (508 or the abutment surface between the

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threaded prongs); a fastener (**40, Figure 1**) also having threads (**43**) and configured to be disposed within the channels. **[Second Interpretation]** a staple (**506, Figures 16 and 17**) an aperture is inherent between the abutment/graft holding surface (between prongs) of the staple and the surface of the bone screw (**10**) should soft tissue pass through (soft tissue is not positively recited).

Kohrs et al further disclose a method of the first interpretation of forming an aperture within a bone; channels (**24a/b**) in an exterior surface of the implant (**10**); coupling the implant to a driver (**506**); driving the implant into the aperture; forming an implant engaging surface within the aperture; and coupling soft tissue to the implant (inherent) because the body is full of soft tissue, the device is clearly indirectly coupled to soft tissue located elsewhere in the body.

Claims 9-12, 20, 21, 23-29, and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenfield (US Patent 5,584,835).

Greenfield discloses a system comprising: an implant (**50**) having outer threads; an exterior top surface defining a channel; a driver (**205**) having a cutting portion (**207**) and a driving portion (unseen handle or body portion to allow for easier pressure application); a staple (**51**) having an upward locking surfaces (**55**) to engage with internal locking surfaces with in implant (**50**); and a graft (**63**) interposed between the staple (**51**) and implant (**50**).

Greenfield discloses a method (between **Figures 3, 8, and 9** as well as throughout the specification) comprising: forming an implant engaging surface within a bone aperture while driving an implant (**50, 101**) into a bone aperture with driver (**205**);

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inserting a staple (51, 90) into a slot (100) which is located within the bone aperture when implant (50, 101) is in place, the staple (51, 90) directly engages the implant and indirectly engages the bone aperture; the slot (100) is formed within the bone aperture once implant (50, 101) is driven into place; channels inherently exist in implant (50, 101) due to the disclose (Column 8, Lines 44-67) where Greenfield discloses that a counterclockwise rotation will back out the staple (51, 101); the channels are normally engaged by anchor locking members (55); thus when the staple is inserted, it is inserted into the slot (100) as well as the channels; a graft (63) is placed between (Figure 9) a graft holding face (53) of the implant (50, 101) and a graft holding surface (58) of the staple (51, 90).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenfield. Greenfield discloses all of the claimed limitations except for providing for a bioabsorbable bone screw. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a bioabsorbable material, since it has been held that to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to the Greenfield reference filed October 11th, 2006 have been fully considered but they are not persuasive. Applicant argues that element (207) is not a cutting portion. If one so desired, it could cut into a material, however, the original interpretation of cutting indirectly with the threading (50) is still appropriate. All that applicant states is that the cutting portion be configured to form an implant-engaging surface. It does not say that it must do so directly. Clearly the rotational component of element (207) is what creates the implant-engaging surface from threading (50). The pushing of the overall device (from the handle) creates the driving component. In regard to claims 20 and 32, the same argument applies. Applicant does not state that it directly engages both the implant and bone aperture.

Applicant's arguments with respect to the remaining claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
December 16th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER